

# Notice of Allowability

Application No.

10/747,671

Examiner

Raymond J. Henley III

Applicant(s)

RAO ET AL.

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed February 26, 2007.
2. ☒ The allowed claim(s) is/are 1-14.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. Drawings filed 12/30/03 are acceptable

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's ~~Amendment~~ Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Single Document

RAYMOND HENLEY III  
PRIMARY EXAMINER

ALU 10/14

## EXAMINER'S COMMENTS/REASONS FOR ALLOWANCE

### *Comments*

Applicants' amendment filed February 26, 2007 has been received and entered into the application. Accordingly, claim 1 has been amended. The election of species requirement as maintained in the previous Office action is withdrawn.

Claims 1-14, all claims pending, have been considered. For the reasons below, the rejections set forth in the previous Office action under 35 U.S.C. §§ 102 and 103, as well as the judicially-created doctrine of obviousness-type double patenting, have been overcome by such amendment and thus are hereby withdrawn. For the reasons, *infra*, claims 1-14 are deemed allowable.

### *Reasons for Allowance*

The following is an examiner's statement of reasons for allowance:

The present invention is directed to a method for inhibiting osteoclast formation in a subject in need thereof which comprises the step of administering a pharmaceutically effective amount of an isolated compound of the general formula  $ZOC-(CRR)_m-COOH$ , where Z and each R are as defined throughout the disclosure and claims of the specification. The compounds of Applicants' invention are characterized as a class of acidic amino acid/dicarboxylic acid derivatives, including sulfonic acid/sulfate derivatives of naturally occurring amino acids and their amides, (*e.g.*, see the specification at page 1, lines 8-10).

The closest teaching in the art to the present invention is set forth in Wani et al., (U.S. Patent No. 6,905,710), where a method for inhibiting osteoclast formation is disclosed. Inhibiting osteoclast formation is accomplished by Wani et al. by administering an effective

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amount of a hydrosylate extract obtained from Indian green mussel, (*e.g.*, *Perma viridis*). Wani et al. fail to expressly disclose the compounds which constitute the mussel extract. However, in light of Applicants' disclosure at page 8, line 22 – page 9, line 19, it is reasonable to believe that the compounds of Applicants' claims are inherently present in the extract of Wani et al.

The presently claimed method is not anticipated or would not have been obvious over the method of Wani et al. because in the present claims, it is required that the compound(s) be *isolated*. While this term is not defined in the present specification, this term is common in the English language lexicon and, in the field of chemistry, means “in an uncombined or pure state”. The term “isolated” imparts patentable distinction to the presently claimed subject matter because it excludes those substances which are not the presently claimed compounds but are also necessarily present in the mussel abstract taught by Wani et al.

For the above reasons, and not those reasons which are otherwise and set forth in Applicants' amendment at pages 11-13, claims 1-14 are deemed to not be anticipated by, obvious from or patentably indistinct from that claimed in Wani et al. and thus are in condition for allowance.

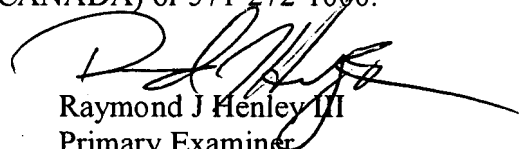
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J Henley III  
Primary Examiner  
Art Unit 1614

May 25, 2007